

The David F. Kelly Bioethics Lectures

www.mpatraoneves.pt

www.mpatraoneves.pt

The role of Bioethics in policy-making in the European Union

www.mpatraoneves.pt

www.mpatraoneves.pt

www.mpatraoneves.pt

www.mpatraoneves.pt

M. Patrão Neves
m.patrao.neves@gmail.com
www.mpatraoneves.pt

The role of Bioethics in policy-making in the EU

The different features of bioethics matter because:

- it is not credible for bioethics to have different kinds of models among which one could choose according to one's own interest concerning a specific thematic;
- we need to build a global bioethics that has to take into consideration the different perspectives on bioethics around the world.

In this context, European perspective matters doubly because:

- future bioethicists need to understand bioethics around the world;
- the European Union comprises 28 member states and can be presented as a living laboratory for a global bioethics.

The role of Bioethics in policy-making in the EU

1. Bioethics and policy making at the national level:
the first initiatives

2. Bioethics and policy making at the European
level: institutions and achievements

3. Bioethics and policy making at the European
Union level: functioning and challenges

3.1. how does the EU work

3.2. what role does bioethics play

3.3. which cases better illustrate EU procedures



The role of Bioethics in policy-making at the national level: the first initiatives.

The role of Bioethics in policy-making in the EU

(1) at the national level: the first initiatives

Bioethics was born in the USA in 1970 (Potter; 1971, Hellegers; 1962, Scribner) and the first initiatives to influence policy making were:

1966, recommendation of the establishment of Institutional Review Boards/IRB (1974);

1974-78, National Commission for the Protection of Human Subjects of Biomedical Research (1978, Belmont Report), *ad-hoc*;

1975, recommendation of the establishment of Institutional Ethics Committees/IEC (1983).

The role of Bioethics in policy-making in the EU

(1) at the national level: the first initiatives

Bioethics was born in Europe after 1978 (birth of Louise Brown) and the first initiatives to influence policy making were:

1982-84, Warnock Commission, *ad-hoc* (UK);

1983, National Consultative Ethics Committee on Health and Life Sciences, permanent (France): multidisciplinary, pluralist, independent, advisory;

1994, France approved the first laws on bioethics;

2004, France established a Law on Bioethics (2011).

The role of Bioethics in policy-making in the EU

(1) at the national level: the first initiatives

www.mpatraoneves.pt

1986: Sweden

1987: Denmark

1990: Portugal, Italy

1991: Finland

1991: Austria

www.mpatraoneves.pt

1993: Belgium

2001: Germany

www.mpatraoneves.pt

2002: Ireland

www.mpatraoneves.pt

1992: Council of Europe

1993: International Bioethics
Committee / UNESCO

www.mpatraoneves.pt

1998: Intergovernmental
Bioethics Committee /
UNESCO

www.mpatraoneves.pt

www.mpatraoneves.pt

The role of Bioethics in policy-making in the EU

(1) at the national level: the first initiatives

www.mpatraoneves.pt

National *ad hoc* commissions

tend to be centered in specific problems, with restricted goals and of a very pragmatic nature (they tend to find/propose new ways of action, that can be acceptable by the scientific community and by society in general, appealing to a procedural methodology not necessarily strong from the foundational or theoretical point of view).

Their function is more that of establishing rules of practice.

www.mpatraoneves.pt

National permanent commissions

tend to consider a wide range of problems, with different kinds of goals, and of a philosophical and legal nature (they tend to involve in deep philosophical issues, drawing very general and even abstract principles not easily applied to cases but leading to legislation).

Their function is advisory and educational, contributing also to the production of new legislation or the reviewing of some already existing.

The role of Bioethics in policy-making in the EU

(1) at the national level: the first initiatives

The specific conditions that assisted the birth and early development of bioethics in continental Europe decided its significant influence in policy-making, through the mediation of a legislation process.

Ethics committees:

- national dimension (promotes coherence, standardization and, therefore, strengthens the validity of advices);
- permanent status (always available, covers all issues, becoming more influential and more independent);
- its very existence compels politicians to ask for its advice and presses them to comply with.



www.mpatraoneves.pt

The role of Bioethics in policy-making at the European level: institutions and achievements

www.mpatraoneves.pt

The role of Bioethics in policy-making in the EU

(2) at the European level: institutions and achievements

The creation of permanent ethics committees expanded from national to international bodies, strengthening its legal and political weight - what also happened first in Europe.

The Council of Europe/CoE (1949), that promotes human rights in Europe, was the first international institution to establish an international body to address bioethical issues:

1985 - The Committee of Experts on Bioethics/CAHBI (*ad-hoc*) is responsible for the intergovernmental activities of the CoE in bioethics, also identifying the legal and political gaps produced by biotechnological advances in life sciences, drawing common guidelines to all 47 member states to deal with the new situations created by these advances, guaranteeing the person's integrity and the respect for human dignity.

The role of Bioethics in policy-making in the EU

(2) at the European level: institutions and achievements

www.mpatraoneves.pt 1992 – it became permanent under the name of Steering Committee on Bioethics/CDBI. www.mpatraoneves.pt

www.mpatraoneves.pt 2012 – following the reorganization of intergovernmental bodies at the CoE, the CDBI was restructured into the Committee on Bioethics/DH-BIO, having also the responsibility to: “assess ethical and legal challenges raised by developments in the biomedical field; co-operate with the European Union and relevant intergovernmental bodies, in particular with a view to promoting consistency between the normative texts.” www.mpatraoneves.pt

The role of Bioethics in policy-making in the EU

(2) at the European level: institutions and achievements

1997 – **Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine** (the only international treaty in the fourth generation of human rights).

www.mpatraoneves.pt

www.mpatraoneves.pt

Protocols (deepened the consensus, but the diversity of opinions in many issues persisted):

1998 – **Prohibition of Cloning Human Beings (1998)**

www.mpatraoneves.pt

www.mpatraoneves.pt

2002 – **Transplantation of Organs and Tissues of Human Origin**

2005 – **Biomedical Research**

2008 – **Genetic Testing for Health Purposes**

www.mpatraoneves.pt

www.mpatraoneves.pt

(2011; under public consultation) – **Protection of human rights and dignity of persons with mental disorders**

The role of Bioethics in policy-making in the EU

(2) at the European level: institutions and achievements

The European Court of Human Rights (ECtHR) (1959) also plays an important role in what concerns bioethics. Ruling only about human rights issues (wide scope), its judgments are binding (establishing jurisprudence for the particular case under deliberation).

The admissibility of individual complaints, facilitates the presentation of bioethical cases such as:

- Reproductive rights and Medically assisted procreation, Assisted suicide, Retention of finger print, cellular samples and/or DNA by authorities, Right to know one's own biological identity.

2015 (Parrillo vs. Italy) ECtHR recalled that "*human embryos cannot be reduced to "possessions"*" and rejected the complaint.

2015 (Lambert vs. France) ECtHR accepted the French legal decision to stop intravenously feeding.

The role of Bioethics in policy-making in the EU

(2) at the European level: institutions and achievements

The national ethics committees model spreads in Europe, and the previously highlight advantages strengthen through:

- broader and more diverse social participation (more pluralistic and democratic);
- wider geographic field of application (stronger validity);
- wider and stronger standardization of norms (stronger coherence, influence and independence);
- first Convention on bioethics (legally binding);
- one court applying the same rules and procedures (human rights);
- the required development of bioEthics into bioLaw and into bioPolitics, in this sequence, is reinforced.

The role of Bioethics in policy-making in the EU

(2) at the European level: institutions and achievements

The influence of ethical (national and international) deliberations is measured by their translation into legal regulations and political implementation:

- BioEthics builds the ethical consensus; the wider they are, the narrower their substance is; this ethical minimum needs the strength of law to be enforced;
- Biolaw converts the ethical consensus into legal dispositions to be implemented by all (although it remains frequently as soft law);
- Biopolitics takes the legislative initiative and engages the right means for its general application into public policies.



www.mpatraoneves.pt

The role of Bioethics in policy-making

www.mpatraoneves.pt

at the European Union level: functioning and challenges

www.mpatraoneves.pt

3.1. how does the EU work

www.mpatraoneves.pt

3.2. what role does bioethics play

www.mpatraoneves.pt

3.3. which cases better illustrate EU procedures

www.mpatraoneves.pt

www.mpatraoneves.pt

The role of Bioethics in policy-making in the EU

(3.1) at the Union level: functioning and challenges

The EU is a geographic, an economic, a political reality, gathering 28 member states in a shared citizenship, organized by many institutions, with a high level of representation and, therefore, complex and slow functioning.

www.mpatraoneves.pt

(some) **EU Institutions:**

www.mpatraoneves.pt

- European Commission

- European Council

www.mpatraoneves.pt

- European Parliament

www.mpatraoneves.pt

- Council of the European Union European Council

- Court of Justice of the European Union

www.mpatraoneves.pt

- European Court of Auditors

www.mpatraoneves.pt

- European Central Bank

The role of Bioethics in policy-making in the EU

(3.1.) at the EU level: functioning and challenges

European Commission

Brussels, 1 + 1 + 26 commissioners

Role: Executive (and supervision),
legislative initiative.

European Council / Council of the EU

Brussels, 28 Head of State/ministers

Role: political direction and priorities;
legislative, coordination of policies.

European Parliament

Strasbourg, 751 members

Role: legislative, supervisory, and
budgetary.



The role of Bioethics in policy-making in the EU

(3.1.) at the Union level: functioning and challenges

Functioning of the three main European Institutions



(1) The Commission takes the initiative to present a legislative text to (2) the Parliament and to (3) the Council, simultaneously. The Parliament (4) approves the proposal with its own amendments and presents them to the Council that might approve them too: (5) if so, legislation is approved.

The role of Bioethics in policy-making in the EU

(3.2.) at the Union level: functioning and challenges

The European Commission has the power of initiative also in what concerns bioethical issues. Therefore:

1991 - it created the *ad-hoc* Group of Advisers to the European Commission on the Ethical Implications of Biotechnology/GAEIB to promote ethical reflection and take it into account on the decision-making process;

1997 - it was restructured into the permanent European Group on Ethics in Science and New Technologies/EGE, an independent, pluralist, and multidisciplinary, advisory body advising the EC on ethics in science and new technologies in connection with community legislation or policies.

The role of Bioethics in policy-making in the EU

(3.2.) at the Union level: functioning and challenges

www.mpatraoneves.pt

www.mpatraoneves.pt

(some) Opinions:

2002 - Ethical Aspects of Patenting Inventions Involving Human Stem Cells

www.mpatraoneves.pt

www.mpatraoneves.pt

2003 - Ethical Aspects of Clinical Research in Developing Countries

2004 - Ethical Aspects of Umbilical Cord Blood Banking

www.mpatraoneves.pt

www.mpatraoneves.pt

2005 - Ethical Aspects of ICT Implants in the Human Body

2007 - Ethical Aspects of Nanomedicine;

2009 - Ethics of Synthetic Biology

www.mpatraoneves.pt

www.mpatraoneves.pt

2015 - Ethics of New Health Technologies and Citizen Participation

The role of Bioethics in policy-making in the EU

(3.2.) at the Union level: functioning and challenges

The President of the Commission asks for an Opinion on a specific topic previewed for future legislation and takes it into account in its proposal (2012, Information and Communication Technologies; 2013, Assessing, Research, Production and Use of Energy; 2014, Security and Surveillance Technologies).

The EGE also has the power of initiative:

www.mpatraoneves.pt

www.mpatraoneves.pt

(some) Statements

2013 - Clinical Trials Regulation

www.mpatraoneves.pt

2015 - Research Integrity

www.mpatraoneves.pt

2016 - Gene Editing

The role of Bioethics in policy-making in the EU

(3.2.) at the Union level: functioning and challenges

European Court of Justice/ECJ (the highest court of the EU) ensures that EU law is interpreted and applied the same in every EU country, and settles legal disputes between national governments and EU institutions (in certain circumstances, can be used by individuals, companies or organizations to take action against an EU institutions).

2011 (Oliver Brüstle vs. Greenpeace) ECJ ruled that embryonic stem-cells cannot be patented within the European Union, noting that the embryo exists from fertilization itself and that if embryos are destroyed to obtain these cells, the protection of human dignity is violated.

The role of Bioethics in policy-making in the EU

(3.3.) at the Union level: functioning and challenges

A selection of cases was made to illustrate the impact of bioethics in legislative initiatives and policy making, covering different fields, and presenting different approaches:

- Protection of Animal used for scientific purposes (**animal** level; bioethics determined the Directive, a legal document with political implications);
- Cultivation of genetically modified organisms/GMO (**plants** level; there was no bioethical, neither political agreement, and the legal ruling reflects it);
- Clinical Trials on medicinal products for human use (**human** level; bioethics was surpassed at the beginning of the process and reintroduced later).

The role of Bioethics in policy-making in the EU

(3.3.) at the Union level: functioning and challenges

Directive 2010/63/EU revising Directive 86/609/EEC on the protection of animals used for scientific purposes was adopted on 22 September 2010.

05/11/2008: Adoption by Commission

07/11/2008: Transmission to Council and to the Parliament

05/05/2009: EP opinion on 1st reading

10/05/2010: Council agreement

13/09/2010: Approval by the Council of the EP amendments at 2nd reading

22/09/2010: Signature by the President of the EP and by the President of the Council

The role of Bioethics in policy-making in the EU

(3.3.) at the Union level: functioning and challenges

The new European Union Directive obliges Member States to:

- replaced (by other methods of research), reduced (number of animals used and reused them), refined (of breeding, accommodation, care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm);
- applies to all live non-human vertebrate animals (foetal forms of mammals as from the last third of their development), certain invertebrates which are likely to feel pain (cuttlefish, octopus, etc.);
- special restrictions to non-human primates; forbids the use of great apes; endangered species; animals taken from the wild;
- standards of treatment, killing, the use of anesthesia, rehoming;
- animal welfare-body.

The role of Bioethics in policy-making in the EU

(3.3.) at the Union level: functioning and challenges

Directive 2015/412/EU of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

13/07/2010: Adoption by Commission

14/07/2010: Transmission to Parliament and to the Council

05/07/2011: EP opinion on 1st reading

12/06/2014: Council agreement

02/03/2015: Approval by the Council of the EP amendments at 2nd reading

11/03/2015: Signature by the President of the EP and by the President of the Council

The role of Bioethics in policy-making in the EU

(3.3.) at the Union level: functioning and challenges

Before, Member States could provisionally ban or restrict the use of a GMO on their territory only if they had fresh evidence that the organism concerned constituted a risk to human health or the environment.

The new Directive allows Member States to ban or restrict the cultivation of GMO on their territory, provided that such measures are reasoned, proportional and non-discriminatory and, based on compelling grounds such as:

- (a) environmental policy objectives;
- (b) town and country planning;
- (c) land use;
- (d) socioeconomic impacts;
- (e) avoidance of GMO presence in other products;
- (f) agricultural policy objectives;
- (g) public policy (cannot be used individually)

The role of Bioethics in policy-making in the EU

(3.3.) at the Union level: functioning and challenges

Regulation 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use:

2008 (December), Communication of the Commission announcing that an assessment would be made of the application of the Clinical Trials Directive 2001/20/EC;

2009 (October)-2010 (January), Public consultation;

2010, Roadmap for a legislative proposal on a Regulation/Directive amending the Clinical Trials Directive 2001/20/EC of the Commission impact assessment, setting out the main structure and the next steps;

2011 (February), Public consultation on a concept paper on the revision of the Clinical Trials Directive 2001/20/EC.

The role of Bioethics in policy-making in the EU

(3.3.) at the Union level: functioning and challenges

2012 (July), the Commission adopted the Proposal for the European Parliament and of the Council on Clinical Trials on medicinal products for human use, accompanied by an impact assessment report.

The proposal was submitted to the European Parliament and the Council who engaged in ordinary legislative procedure:

2013 European Group of Ethics Proposal for a Regulation of the European Parliament and the Council on Clinical Trials;

2014 (April) adopted, and published in the Official Journal on May 2014. The Regulation entered into force on June 2014 but will be applied no earlier than May 2016.

The role of Bioethics in policy-making in the EU

(3.3.) at the Union level: functioning and challenges

Regulation 536/2014 (is not a Directive):

- aims to attract clinical trials, by making the procedure simpler (less bureaucracy, single application) and faster (shorter authorization time, tacit approval), therefore cheaper and more efficient;
- aims to reinforce harmonization, simplification, facilitation and centralization of the procedures and decentralization of ethical assessment in order to strengthen EU competitiveness;
- the proposal did not refer to Ethics Committees; now it transfers the authority of ethical evaluation to the member states (competent bodies have 10 days to assess ethical aspects);
- the proposal stated that the refusal to participate from incapacitated adults or minors should be taken under consideration; now in emergency situations it is possible to skip informed consent; minors can be involved without a previous direct benefit.

The role of Bioethics in policy-making in the EU

(3) at the Union level: functioning and challenges

The complex functioning of the EU presents challenging situations for the impact of bioethics in policy making. Nevertheless:

- the most effective procedure is to go from bioEthics, to bioLaw to bioPolitics;
- when other interests disrupt this sequence, there are proper means to ensure that bioethical concerns are taken into consideration such as “public consultation”, lobbying and NGOs; Parliament’s work;
- Bioethics keeps on having a significant influence in policy-making, although the temptation to skip it is also present.

www.mpatraoneves.pt

www.mpatraoneves.pt

www.mpatraoneves.pt

www.mpatraoneves.pt

thanks

www.mpatraoneves.pt

www.mpatraoneves.pt

www.mpatraoneves.pt

www.mpatraoneves.pt

www.mpatraoneves.pt